



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

September 12, 2014

Merit Medical, Inc.  
c/o Ms. Siobhan King  
Regulatory Affairs Specialist II  
Parkmore Business Park West  
Galway, Ireland

Re: K140608

Trade/Device Name: InQwire®  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guidewire  
Regulatory Class: Class II  
Product Code: DQX  
Dated: August 14, 2014  
Received: August 18, 2014

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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## Section 4 Indications for Use Statement

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**510(k) Number (if known):** K140608

**Device Name:** Merit Heparin-coated InQwire® Diagnostic Guide Wire

**Indications for Use:**

Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)




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## 510(k) Summary

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### General Provisions

Submitter Name: Merit Medical Systems, Inc.  
 Address: 1600 West Merit Parkway  
 South Jordan, UT 84095  
 Telephone Number: (+353) 91 703700 (3061)  
 Fax Number: (+353) 91 680 104  
 Contact Person: Mark Mullaney  
 Registration Number: 1721504

Correspondent Name: Merit Medical Ireland Ltd.  
 Address: Parkmore Business Park West  
 Galway, Ireland  
 Telephone Number: (+353) 91 703700 (3052)  
 Fax Number: (+353) 91 680 104  
 Contact Person: Siobhan King  
 Date of Preparation: 06/03/2014  
 Registration Number: 9616662

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### Subject Device

Trade Name: InQwire®  
 Common/Usual Name: Merit Medical Guide Wire  
 Classification Name: 21 CFR 870.1330 Catheter guide wire

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### Predicate Device

#### Premarket Notification Predicate#1:

Trade Name: InQwire®  
 Classification Name: 21 CFR 870.1330 Catheter guide wire  
 Premarket Notification: K822586  
 Manufacturer: Merit Medical Systems, Inc.

#### Premarket Notification Predicate#2:

Trade Name: InQwire®  
 Classification Name: 21 CFR 870.1330 Catheter guide wire  
 Premarket Notification: K133230  
 Manufacturer: Merit Medical Systems, Inc.

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### Classification

Class II  
 21 CFR 870.1330 Catheter guide wire  
 FDA Product Code: DQX  
 Review Panel: Division of Cardiovascular Devices

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### Intended Use

Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

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Merit Heparin-coated InQwire<sup>®</sup> Diagnostic Guide Wires are intended to facilitate the placement of devices during diagnostic and interventional procedures. The guide wires have a continuous PTFE (Polytetrafluoroethylene) coated coil, inside core wire and a safety wire. The core wire is fixed at the proximal end only and extends to a specified distance from the distal end. The distal segment of the core wire has a profiled taper. The core wire enhances the stiffness of the guide wire. The safety wire extends the full length of the guide wire and is welded at both the distal and proximal end. The safety wire is designed to provide integrity and ensures that the guide wire components remain together. A Benzalkonium Heparin coating is applied over the PTFE coating.

The Heparin-coated InQwire<sup>®</sup> Diagnostic Guide Wires are offered in 0.035 inch or 0.038 inch outer diameter with different tip configurations (straight or J-tip), single ended or double ended (either end of the wire can be placed into the patient), standard or firm shaft, and are available in lengths from 70cm to 180cm. The wire is placed inside a loop flush dispenser, also referred to as a hoop. The dispenser has a female Luer connection which facilitates solution flushing through the hoop to hydrate the guide wire. The guidewires are secured in the hoop dispenser by a locking J-tip straightener.

**Device  
Description**

This modification details a supplier process change relating to removal of perfluorooctanoic acid (PFOA), used in the manufacture of the PTFE (Polytetrafluoroethylene) coating. More specifically PFOA is a processing aid used for the polymerization process of PTFE, which is flashed off during the oven curing process and therefore not part of the finished Heparin-coated InQwire<sup>®</sup> Diagnostic Guidewire. The PTFE coating formulation has changed – PFOA has been removed as a processing aid and replaced with GenX. The oven curing process which cures the coating and flashes off the PFOA remains unchanged. The manufacturing process within Merit has not changed. Due to environmental concerns relating to PFOA, the U.S. Environmental Protection Agency has instructed that all processors of PTFE no longer make, buy or use PFOA (2010/2015 PFOA Stewardship Program). PFOA material is used in the manufacture of both the intermediate layer and top layer of the PTFE (Polytetrafluoroethylene) coating. The removal of PFOA from Merit's non Heparin-coated InQwire<sup>®</sup> Diagnostic Guide Wires was previously assessed under Special 510(k) Premarket Notification, K133230. The only difference between the Heparin-coated InQwire<sup>®</sup> Guidewires and the non-Heparin coated InQwire<sup>®</sup> Guidewires, K133230, is the addition of a Benzalkonium Heparin coating applied over the PTFE coating. No changes have been made to the actual heparin coating. The same design and material characteristics that were qualified in K133230, also apply to the heparin-coated InQwire<sup>®</sup> Diagnostic Guidewires.



### Comparison to Predicate

Technological characteristics of the subject Merit Medical Heparin-coated InQwire® Diagnostic Guide Wire are substantially equivalent to Predicate Device#1, the Merit Medical Heparin-coated InQwire® Diagnostic Guidewire [K822586] and Predicate Device#2, the Merit Medical non Heparin-coated InQwire® Diagnostic Guidewire [K133230]. The difference between the subject device and Predicate Device# 1 relates to the removal of perfluorooctanoic acid (PFOA), used in the manufacture of the PTFE (Polytetrafluoroethylene) guide wire coating. The guide wire design and indications remain unchanged. Other than the addition of a Benzalkonium Heparin coating applied over the PTFE coating, the subject device and Predicate Device#2 are identical. The guide wire design and indications remain unchanged. Predicate Device#2, the Merit Medical non Heparin-coated InQwire® Guidewire is the predicate for the performance testing parameters.

### Safety & Performance Tests

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Merit Heparin-coated InQwire® Diagnostic Guide Wire was conducted based on risk analysis. A battery of testing was conducted in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

Where appropriate, the tests were based on the requirements of the following documents:

- FDA guidance Coronary and Cerebrovascular Guide Wire Guidance January 1995.
- ISO 11070:1998, *Sterile Single-Use Intravascular Catheter Introducers*.
- ISO 11135-1:2007 *Sterilization of health care products-Ethylene oxide- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*.
- ASTM F1980-07 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.

The Merit Heparin-coated InQwire® Diagnostic Guide Wire was compared to the predicate device(s) for various performance attributes that support substantial equivalence of the device. The difference in coating between the modified device and the cleared device, the Merit Medical Heparin-coated InQwire® Diagnostic Guidewire, [K822586] has raised no new issues. Performance testing was based on Predicate Device#2, the Merit Medical non Heparin-coated InQwire® Diagnostic Guidewire, [K133230].

The following is a list of all significant testing that was successfully



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completed:

- Surface
- Coating Adherence/Integrity
  - Fracture Test
  - Flexing Test
  - Coil Lubricity Test
- Catheter Compatibility
- Biocompatibility

All test results were comparable to the predicate devices and the subject Merit Heparin-coated InQwire<sup>®</sup> Diagnostic Guide Wire met the predetermined acceptance criteria applicable to the safety and effectiveness of the device. This has demonstrated the subject device is substantially equivalent to predicate devices.

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**Summary of  
Substantial  
Equivalence**

Based on the Indications for Use, design, safety and performance testing, the subject Merit Medical Heparin-coated InQwire<sup>®</sup> Diagnostic Guide Wire is substantially equivalent to the predicate devices, the cleared Merit Medical Heparin-coated InQwire<sup>®</sup> Guidewire, K822586, and the Merit Medical non Heparin-coated InQwire<sup>®</sup> Diagnostic Guide Wire, K133230.

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